K 130383

5. 510(k) Summary

APR 0 9 2013

Date Prepared:

March 12, 2013

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, Connecticut 06902

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Contact: Jyh-Shyan Lin

Device Trade Name:

Synapse 3D Cardiac Tools

Device Common Name:

Medical Image Processing and Analysis Software

Regulation Number:

21 CFR 892.2050

Device Classification:

Class II

Device Classification Name:

Picture Archiving and Communications System (PACS)

Panel:

Radiology

Product Code:

LLZ

Date Received:

TBD

Decision Date:

TBD

Decision:

TBD

Predicate Device:

- Synapse 3D Cardiac Tools (K120636), FUJIFILM Medical Systems U.S.A., Inc.
- 3mensio Structural Heart / Vascular (K120367), Pie Medical Imaging BV

Description of the Device

Synapse 3D Cardiac Tools is the updated version of previously-cleared Synapse 3D Cardiac Tools software (cleared by CDRH via K120636 on 07/05/2012).

Synapse 3D Cardiac Tools is used in addition to the Synapse 3D Base Tools (K120361) to analyze the images acquired from CT and MR. Synapse 3D Cardiac Tools is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning of DICOM compliant medical images.

Synapse 3D Cardiac Tools is an application that supports the cardiac function, cardiac fusion, and coronary artery analysis of both the computed tomography (CT) and magnetic resonance (MR) images. Synapse 3D Cardiac Tools also supports the calcium scoring for non-contrast CT images.

Unchanged Applications from the cleared version K103465

(1) Cardiac Function (CT)
Cardiac Function (CT) is an application for cardiac function evaluation which obtains the boundary between left ventricle and cardiac wall from CT left ventriculography images retrieved from multiple time phases and calculates ejection fraction, end-diastolic volume, end-systolic volume, stroke volume, etc.

(2) Cardiac Function (MR)
Cardiac Function (MR) is an application for cardiac function evaluation which obtains the boundary between left ventricle and cardiac wall from non-contrasted MR images retrieved from multiple time phases and calculates ejection fraction, end-diastolic volume, end-systolic volume, output volume per beat, etc.

(3) Coronary Artery Analysis (CT)
Coronary Artery Analysis (CT) is an application using CT coronary arteriography images to extract the path of the target blood vessels and to perform coronary artery evaluation.

(4) Calcium Scoring
The calcium scoring is an application which uses non-contrasted CT images to display the calcification area in the coronary artery with color separation and calculates the calcification quantitative values using the Agatston score method.

(5) Cardiac fusion
Cardiac fusion is an application to create an image having the mutual characteristics of source images of heart. Source images could be original image of CT, MR or NM and the functional image derived from the original image.

Unchanged Applications from the cleared version K120636

(1) Coronary Artery Analysis (MR)

Coronary Artery Analysis (MR) is an application using non-contrast MR heart images to extract the path of the target blood vessels and to perform coronary artery evaluation. The detail features available in this application are very similar to Coronary Artery Analysis (CT).

New Application in this submission

(1) Aortic Valve Analysis

Aortic Valve Analysis (CT) is an application using contrast-enhanced CT images for visualization of the heart, aorta regions, and contour of the aorta, measurement of the vicinity of the aortic valve, measurement of the calcification area in the aorta.

In addition to the common image processing functions (such as window width and window level, zooming, panning, flip, rotation, adding annotations on an image, measurement of lengths, areas, etc.), the following image processing tools are available to support the cardiac analysis of the CT and MR images. These tools belong to and are provided by Synapse 3D Base Tools (K120361) that is used with Synapse 3D Cardiac Tools (this submission).

- SUV evaluation: SUV average, standard deviation, etc. can be measured.
- Extraction and Deletion of 3D objects: Editing of mask areas using the smart cut feature.
- 3D clipping: The display area can be specified for 3D display.
- Organ segmentation and removal: Organs and other areas of interest in the image data can be segmented or removed.
- Mask editing: The mask area can be edited by lines drawn in freehand.
- CPR: CPR images can be created along a specified center line.
- Reformat: Plane images in any direction can be created.
- Creation of video files: Video files with 2D or 3D display can be created.
- Surface display: A polygon model of an image can be created.

Indication for Use

Synapse 3D Cardiac Tools is medical imaging software used with Synapse 3D Base Tools that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Cardiac Tools accepts DICOM compliant medical images acquired from a variety of imaging devices including, CT, MR, NM, and XA.
This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.
Addition to the tools in Synapse 3D Base Tools, Synapse 3D Cardiac Tools provides the tools for specific clinical applications which provide targeted workflows, custom UI, targeted measurements and reporting functions including:

- Functional cardiac analysis for CT left ventriculography images: which is intended to evaluate the functional characteristics of heart
- Functional cardiac analysis for non-contrast MR heart images: which is intended to evaluate the functional characteristics of heart
- Coronary artery analysis for CT coronary arteriography images: which is intended for the qualitative and quantitative analysis of coronary arteries
- Coronary artery analysis for MR heart images: which is intended for the qualitative and quantitative analysis of coronary arteries
- Calcium scoring for non-contrast CT heart images: which is intended for non-invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms
- Cardiac Fusion: which is intended to analyze cardiac anatomy and pathology with a fused image of functional data (e.g. NM image, Bulls eye) and anatomical data.
- Aortic Valve Analysis for contrast CT heart images: which is intended for visualization of the heart, aorta regions, and contour of the aorta, measurement of the vicinity of the aortic valve, measurement of the calcification area in the aorta.

Technological Characteristics

The proposed Synapse 3D Cardiac Tools and the predicate devices, Synapse 3D Cardiac Tools (K102636) and 3mensio Structural Heart / Vascular (K120367), are medical application software running on Windows operating system installed on commercial general-purpose Windows-compatible computers. These devices are connected to CT and MR with DICOM standard and retrieve image data via network communications. These devices provide 3D image visualization and manipulation tools for medical images with various user interfaces and measurement tools for analysis of rendered images. Both the Synapse 3D Cardiac Tools and the predicate devices support the workflows, UI, and reporting functions for cardiac analysis and aortic valve analysis.

Synapse 3D Cardiac Tools introduces no new safety or efficacy issues other than those already indentified with the predicate devices. The results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the device is of moderate concern as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices."

Testing

Synapse 3D Cardiac Tools is tested successfully with reference to its Software Requirements Specification, as well as design verification and validation documents and Traceability Matrix document. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the Synapse 3D Cardiac Tools software, which is found to be safe and effective and substantially equivalent to the currently-cleared predicate devices.

Testing involved system level functionality test, segmentation accuracy test, measurement accuracy test, interfacing test, usability test, serviceability test, labeling test, as well as the test for risk mitigation method analyzed and implemented in the risk management process. In addition, we conducted the bench performance testing using actual clinical images to help demonstrate that the proposed device achieved the expected accuracy performance.

Pass/Fail criteria were based on the requirements and intended use of the product. Test results showed that all tests successfully passed.

Conclusion

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject device to be as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2013

JYH-SHYAN LIN
SENIOR MANAGER, REGULATORY, QUALITY AND CLINICAL AFFAIRS
FUJIFILM MEDICAL SYSTEMS USA, INC.
419 WEST AVENUE
STAMFORD CT 06902

Re: K130383
Trade/Device Name: Synapse 3D Cardiac Tools
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 5, 2013
Received: February 14, 2013

Dear Mr. Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

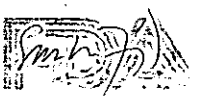
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130383

Device Name: Synapse 3D Cardiac Tools

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K130383